Title of Project: Clinical Decision Support for Mild Traumatic Brain Injury

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1. **Structured Abstract**

Purpose: To pilot a formative process for creating an integrated patient-centered decision aid and clinical decision support (CDS) tool for bedside management of minor head injury in the emergency department (ED).

Scope: Adherence to the Canadian Computed Tomography (CT) Head Rule, a clinical decision rule designed and validated to safely reduce imaging in minor head injury, could decrease the number of CT scans performed in minor head injury by 35%. But in practice, the CCHR has failed to reduce testing, despite its accurate performance. Health information technology can hinder the clinician-patient relationship. Patient-centered decision tools to support the clinician-patient relationship are needed to promote evidence-based decisions.

Methods: User-centered design with practice-based and participatory decision aid development was used to design, develop, and evaluate patient-centered decision support regarding CT use in minor head injury in the ED.

Results: The Concussion or Brain Bleed app is a clinician- and patient-facing electronic tool to guide decisions about head CT use in patients presenting to the ED with minor head injury. This app integrates a patient decision aid and clinical decision support at the bedside on a tablet computer to promote conversations around individualized risk and patients' specific concerns within the ED context. The app was found to have a high degree of patient satisfaction (85%), clinician usability (85.1 system usability score), and clinician acceptability (36.6 Net Promoter Score) in pilot testing.

Key Words: patient-centered clinical decision support, user-centered design, minor head injury, mild traumatic brain injury, concussion, overuse, computed tomography

2. **Purpose**

The long-term goal of this project was to develop and validate an innovative CDS design process that produces CDS that is patient-centered, useful, usable, promotes shared decision-making, and safely reduces resource utilization, costs, and cancer risks from ionizing radiation. The objective of this project was to pilot this formative process by creating a tool that integrates a patient-centered decision aid and CDS at the bedside for the management of minor head injury in the ED. This project aimed to shift paradigms for CDS, decision aids, and the ED patient encounter by bringing CDS to the point-of-care for shared use by the patient and provider. In order to accomplish these objectives, I proposed the following specific aims:

Aim 1. To identify nonclinical, human factors that promote or inhibit the appropriate use of CT in patients presenting to the ED with minor head injury.

Aim 2. To formatively evaluate an electronic tool that not only helps clinicians at the bedside to determine the need for CT use based on the Canadian CT Head Rule but also promotes evidence-based conversations between patients and clinicians regarding patient-specific risk and patients' specific concerns.

Aim 3. To describe the use of the Concussion or Brain Bleed app in a high-volume ED and to establish preliminary efficacy estimates on patient experience, clinician experience, health care utilization, and patient safety.

3. **Scope**

Imaging is the fastest growing part of healthcare spending in the United States, increasing twice as fast as total health care costs. In the ED, use of advanced diagnostic imaging in injured patients has tripled over 10 years, leading to increased health care costs, exposure to unnecessary ionizing radiation, and increased length of stay, without objective evidence of improved patient outcomes. To minimize cost and risk, clinical decision rules have been developed to make safe and efficient decisions at the bedside. The Choosing Wisely initiative and the American College of Emergency Physicians (ACEP) identified avoiding CT use in low-risk minor head injury based on validated clinical decision rules as the top priority for stemming overuse in the ED. This priority is in the setting of continued growth in CT use in minor head injury following implementation of a high-performing, rigorously developed, and validated clinical decision rule.

The Canadian CT Head Rule (CCHR), a clinical decision rule designed to safely reduce imaging

in minor head injury by differentiating mild traumatic brain injury from clinically important brain injury, has been rigorously tested and validated (internally and externally) to be 100% sensitive at identifying patients in need of neurosurgical intervention and is more specific than other decision rules. A prospective cluster-randomized trial to implement a similar prediction rule, the Canadian C-spine Rule, led to a significant decrease in imaging. However, when the CCHR was implemented at the same centers with many of the same patients, CT imaging rates increased from 63% to 68% pre-implementation to 74% to 76% post-implementation. Data from this trial indicate that the CCHR failed to reduce imaging rates due to implementation failure, not rule performance. Specifically, compliance with the CCHR has potential to decrease the number of CT scans performed in minor head injury by 35%.

A conceptual model for understanding emergency physician use of CT in minor head injury proposed that “elements unrelated to standard clinical factors, such as personality of the physician, fear of litigation and of missed diagnoses, patient expectations, and compensation method, may have equal or greater impact on actual decision-making than traditional clinical factors.” Indeed, assurance behavior, providing tests of marginal or no medical value due to physicians’ fear of being sued, is more prevalent in the ED than any other clinical realm.13 Furthermore, CT imaging rates for head injury in the ED are lowest in states that have passed medical liability reform laws. However, other ED-specific factors also contribute to overuse, such as time and volume pressures, a paucity of information, limited therapeutic options, and constraints of disposition, which may contribute to overuse in this situation.

Patient and provider non-clinical, human factors also affect the appropriateness of use of CT in patients presenting to the ED with minor head injury. Patients often have unrealistic expectations of benefits and harms, providers are often poor judges of patient preferences and values, and these factors contribute to overuse of resources that informed patients may not value.

Empathic care requires tools that facilitate conversation between patient and clinician. Unfortunately, contemporary electronic health records (EHRs) tend to impede conversation. The EHR interface physically separates the clinician from the patient, compromising communication. It distracts and decreases eye contact, touch, and decreases patient time with clinicians and focuses almost entirely on physician behavior even if it is patient-specific (and evidence-based). Informing patients directly has rarely been part of the effort. CDS is most effective when it is part of the clinician workflow at the time and location of decision making. Patient decision aids, on the other hand, focus on patients, trying to help them decide among options by clarifying patient values, preferences, and goals and providing the best scientific evidence available to increase

understanding of possible risks, benefits, alternatives, and their associated outcomes. A successful decision aid facilitates conversation between the patient and clinician and improves patient engagement.

Current EHRs prohibit empathic care. Technology must support—not hinder—the clinician-patient relationship. Although paper charts were intuitive and simple, they were criticized for being disorganized and illegible, leading to medical errors. EHRs promised to improve patient safety and outcomes by reducing errors. In the rush to adopt EHRs to qualify for federal incentive payments, clinicians and hospitals adopted products with poor usability and poor integration that impede clinical workflow. The EHR's potential for improving care has not yet been realized. A large-scale study of EHR implementation found no negative association with mortality or adverse events across 17 hospitals. EHR implementation has done harm in other ways. Ratanawongsa et al found high computer use by clinicians to be associated with lower patient satisfaction and communication. Sinsky et al also found that physicians only spend 27% of their time face to face with patients, with 49% of their time spent on the EHR and desk work. In addition, EHR documentation requires an additional 1 to 2 hours daily of after-hour charting. A productivity analysis in the emergency care setting found that data entry accounted for 43% of physician time, requiring 4000 mouse clicks per shift. Furthermore, EHRs in their current form physically obstruct and separate the clinician and patient, denying patients time with their clinician as well as compromising communication and human connection by distracting and decreasing eye contact and touch. We propose that the patient-centered decision support presented here is the first step toward a more empathic medical interface that can support the clinician-patient relationship.

Participants were patients and clinicians recruited from an urban, academic Level I trauma center ED with 103,000 patient visits per year and a satellite ED with 24,000 patient visits per year. Clinicians were recruited from the 48 attending physician faculty, 58 resident physicians, and 47 midlevel providers.

4. **Methods**

Needs Assessment

This was a qualitative study in three phases, each with interview guides developed by a multidisciplinary team. Subjects were recruited from patients treated and released with minor head injuries and providers in an urban academic ED and a satellite community ED. Focus groups of patients (four groups, 22 subjects total) and providers (three groups, 22 subjects total) were conducted until thematic saturation was reached. The findings from the focus groups were

triangulated with a cognitive task analysis, including direct observation in the ED (>150 hours), and individual semi-structured interviews using the critical decision method with four senior physician subject matter experts. These experts were recognized by their peers for their skill in safely minimizing testing while maintaining patient safety and engagement. Focus groups and interviews were audio recorded and notes were taken by two independent note takers. Notes were entered into ATLAS.ti and analyzed using the constant comparative method of grounded theory, an iterative coding process to determine themes. Data were double-coded and examined for discrepancies to establish consensus. Focus groups and interviews were conducted until thematic saturation was achieved. Data collection for each phase continued until no new themes were identified in at least one session. Two note takers were present to take notes in each session. Two digital audio recordings were also created during each session. Immediately following each session, the facilitators and note takers met to debrief and discuss themes that had arisen in the focus groups. Notes were then entered into ATLAS.ti (version 1 for Mac) and analyzed using the constant comparative method of grounded theory, an iterative coding process to determine themes. Analysis of the focus group and critical decision method interview notes first focused on identifying themes, issues, and patterns. Next, coding schemes were established and revised to further develop the categories. This was an iterative process with both the descriptions and the coding manual continually being revised until agreement levels reached at least a moderate level. At least two investigators from the focus groups and cognitive task analysis independently coded the data while listening to the audio recordings using systematic, inductive procedures to generate insights grounded in the views expressed by study participants. All data were cross-referenced with the audio recordings and examined for discrepancies and presented to the entire team to establish consensus. To establish relative importance of domains and themes and trends across groups, the frequency of use of themes was counted and reported per session in each phase of the study.

Development of Initial Prototype

A multidisciplinary team applied the findings from the qualitative study as user requirements for the initial prototype. Primary goals were to promote smooth navigation through screens while completing tasks of patient education, risk communication, and shared decision making in the ED.

Usability Evaluation

Formative usability evaluations were conducted in a simulated environment to observe, record, and analyze a standardized clinician-patient encounter with the prototype. Using a “think aloud” protocol, scripted simulations of patient encounters with clinicians and standardized patients were observed and analyzed Attending emergency physicians were given a case study to use

the prototype while commenting on what they saw, thought, did, and felt. Inferences were made about the reasoning process behind task completion. Afterwards, a usability feedback questionnaire and semistructured interview were conducted to determine the tool's ease-of-use, usefulness, and how the decision-making process was affected by the tool.

Field Testing

To optimize naturalistic decision making under the constraints of the complex, high-pressure ED, field testing was conducted by the research team. ED patients available and amenable to participation were identified by the treating clinicians on duty. The prototype was implemented and reviewed by patients during their clinical encounter when they were not actively under evaluation. Patterns of conversation were analyzed while issues and challenges with the tool's use were noted; all notes and experiences were shared and used to track the performance of successive iterations of the prototype based on content and quality of the conversation between the study clinician and the patient. Patients completed a semistructured interview regarding the tool's content and format within the ED context. The tool was iteratively refined according to ecological interface design to optimize communication of patient-specific risk. After thematic saturation, the wireframe prototype was programmed for use as a Web app on an iPad (Apple Inc).

Beta Testing

Beta testing was conducted by emergency physicians using the interactive prototype during clinical care of ED patients with minor head injury. Physicians described their experience to improve workflow. Structured email interviews were conducted after physicians had seen multiple patients. Survey responses informed the final prototype.

Pilot Testing

We performed a prospective pilot study with a convenience sample of 41 ED patients with minor head injury. Patients were enrolled over a 6-week period (May 23 to July 3, 2017). Patients and clinicians who were eligible and willing to participate used the Concussion or Brain Bleed app and completed a survey to determine the app's baseline efficacy on patient experience, clinician experience, health care utilization, and patient safety. Eligible patients were adults (age 18-65 years) presenting to the ED who had experienced blunt head injury within the last 24 hours who were determined to be at low risk by the CCHR and were being considered for head CT imaging by the treating clinician.

Patient Outcomes

Patient Knowledge

We assessed patient knowledge using a pre- and post-visit survey administered immediately before and after the clinical encounter. In the survey, 9 questions assessed patients' knowledge regarding concussion, their individual risk of structural brain injury, the available diagnostic options, the risks related to radiation exposure associated with a head CT scan, the potential for a CT scan to identify incidental abnormalities that may require further investigation, and reasons to return to the ED for reevaluation should their symptoms worsen after ED discharge. We calculated the percentage of knowledge questions answered correctly to determine the mean difference between knowledge scores before and after use of the intervention.

Decisional Conflict

We measured the patient's degree of conflict with the decision of whether to get a CT scan using the validated Decisional Conflict Scale. The 16 items on this scale are scored on a scale 0 to 4; the items are summed, divided by 16, and then multiplied by 25. The scale ranges from 0 to 100, where higher scores reflect patient uncertainty about the choice.

Trust in the Physician

We measured patients' trust in their clinician using the validated Trust in Physician Scale. This scale has 10 items, which are scored on a scale of 1 to 5; the items are summed, divided by 10, and then multiplied by 100. The scale ranges from 0 to 100, where higher values reflect higher levels of trust in their clinician.

Patient Satisfaction

We measured patients' satisfaction with the way information was shared during the encounter by asking 5 questions using a 7-point Likert scale. For the analysis, we classified satisfaction into satisfied/very satisfied versus other responses.

Clinician Outcomes

Clinician Satisfaction

We assessed clinician satisfaction immediately after the patient encounter via a questionnaire regarding the helpfulness of the app and the clinician's satisfaction with the way information was shared on a 7-point Likert scale. For the analysis, we classified satisfaction into satisfied/very satisfied versus other responses.

System Usability Scale

The System Usability Scale consists of a 10-item questionnaire on a 5-point Likert scale that gives a reliable assessment of usability. The 10 items of the System Usability Scale are scored on a scale of 0 to 4, with each even-numbered question reverse coded. The items are summed and then multiplied by 2.5. Scores range from 0 to 100, where higher scores indicate higher usability.

Net Promoter Score

The Net Promoter Score has been employed across industries to measure how willing a user is to recommend a product or service to others. A higher score on this scale ranging from –100 to 100 can indicate a greater growth rate of the corresponding product or service. We determined the score by first asking the clinician user on a scale from 0 to 10 (0=not likely at all, 10=extremely likely) “How likely are you to recommend the Concussion or Brain Bleed application to a colleague?” If a clinician answered 9 or 10, we categorized them as a “promoter”—someone who would enthusiastically recommend the app to others. If a clinician answered 6 or lower, we considered them to be a “detractor”—someone who would potentially give a negative review to others. The Net Promoter Score is calculated by subtracting the percentage of promoters from the percentage of detractors. We calculated a total Net Promoter Score factoring in all encounters in which the app was used, as well as a first-time user Net Promoter Score and a second-time user Net Promoter Score.

Fidelity Score

We assessed the fidelity with which the intervention was delivered and used as intended using a fidelity checklist of 8 intended actions. The fidelity checklist has been used in the absence of the intervention to check for contamination in the usual-care arm of a trial.

<u>Health Care Utilization and Patient Safety</u>

CT scans were obtained at the ED clinicians’ discretion and interpreted by site faculty radiologists. The main health care utilization outcome was the proportion of patients for whom head CT was obtained in the ED. We also collected data at the time of the ED visit (and confirmed by chart review) on (1) whether the patient was admitted to the hospital, (2) acute findings on CT if obtained, and (3) whether the clinician reported that they would have made the same decision regarding CT imaging without using the app. The RA contacted enrolled patients by telephone or email starting at 7 days after the index ED visit to ensure no outcomes were missed. The 7-day follow-up was based on timing of delayed clinical deterioration and our previous work.

5. **Results**

Aim 1

Between June and July 2013, focus groups of patients (four groups, 22 subjects total) and providers (three groups, 22 subjects total) were conducted until thematic saturation was reached. Between October 2013 and March 2014, over 150 hours of ethnographic direct observation was performed in the ED with the four subject matter exerts. At that point, 15 patient encounters had been observed with an average OPTION score of 13.3 out of a possible score of 48 (95% confidence interval = 10.6 to 16.1). Since qualitative analysis of these encounters did not yield any new data, the cognitive task analysis was shifted from ethnographic observation to interviews in a nonclinical environment. In April 2014, individual critical decision method interviews were conducted with the four experts until thematic saturation was reached. In each phase, these participants met our purposive sampling plan. The focus group patients were representative of the patient population seen in our ED: 23% African American or black; 68% female; 9% Hispanic; and 55% with Medicaid, Medicare, or no health insurance. The focus group providers were representative of our ED physician group: 9% African American or black, 23% Asian, and 14% Hispanic, with an average of 8 years of experience practicing EM. In contrast, the four experts had an average of 23 years of experience practicing EM.

We identified five domains (establishing trust/bedside manner, anxiety, constraints, influence of others, and patient expectations) with 11 key themes and 27 less common themes that affect appropriate use of CT in minor head injury in the ED. Patient engagement in the decision whether or not to obtain CT imaging in minor head injury was the most frequently occurring theme. The engagement that patients desired and experts described was characterized more by empathic caring (reassurance, listening, caring, addressing concerns, etc.) than information sharing (e.g., risk communication) or consensus-based decision-making between the patient and provider.

Discrepancies in the frequency of use of themes are suggestive of trends between groups. For example, patients and experts mentioned the themes of patient engagement, reassurance, identifying and addressing concerns, and patient-specific counseling more frequently than the providers, whereas providers mentioned the ability to identify and manage patient anxiety and tolerance for uncertainty, time constraints (especially that CT is faster and more objective and patient load), influence of other health care providers, patient expectations (in particular expectation of a CT), and that patients may not be capable of an informed decision, more frequently in comparison to themes used by patients and experts. Providers and experts

mentioned provider confidence and experience, influence of others, strategies to dissuade imaging (e.g., radiation as a specter and alliance from other providers), and that it takes too long to “do the right thing,” more frequently than patients. Patients and providers mentioned anxiety, provider risk aversion to a bad outcome (due to foregoing CT, bad outcome for the patient, patient complaint, peer review, and cancer risk from CT), and constraints including time and resources (both departmental and financial), more frequently than experts. Patients mentioned listening and caring for the patient as a person more frequently than providers and experts. Subject matter experts mentioned establishing trust and medical necessity more frequently than patients and providers.

We sought to identify non-clinical, human factors that promote or inhibit the appropriate use of computed tomography in patients presenting to the ED with minor head injury. We found that empathic caring is something that patients want and subject matter experts do well, but with which less experienced providers struggle. Moreover, less experienced providers focus on attempting to identify and manage patient anxiety and tolerance for uncertainty while feeling frustrated by time constraints, the influence of other health care providers, and an inability to meet patient expectations more so than subject matter experts. The knowledge gained from this analysis should be used to inform hypothesis generation to identify and disseminate approaches and design systems that help clinicians establish trust and manage uncertainty within the ED context to optimize computed tomography use. In the meantime, this study reinforces how patients who feel they have been cared for, listened to, and engaged may be more likely to trust their providers and their providers’ recommendations whether or not CT scans are medically necessary.

Aim 2

The Concussion or Brain Bleed app underwent 16 successive revisions with content, process, and format adjustment based on usability, field, and beta testing.

Development of Initial Prototype

The initial prototype followed a visual metaphor of design reminiscent of decision aids on paper cards. After the patient filled out eligibility and questionnaire forms to auto-populate subjective components of the clinical decision rule, 3 sections followed. The first section centered around patient education (information about concussions, CT scans) to be used by the patient alone prior to the clinician’s evaluation and gave the patient the opportunity to flag concerns on a digital checklist. These concerns would later show up in the second section to be used by the clinician with the patient. After completing a CDS checklist, the tool generated patient-specific risk estimates for pertinent outcomes and risk of cancer from a head CT. The final section

involved a process of shared decision making in which patients and clinicians decided together whether to obtain a CT scan, to continue to be observed in the ED, or to go home.

Usability Evaluation

Usability evaluation was conducted 3 times with 9 users. Observation revealed the tool required modification to facilitate conversation between the patient and clinician to be incorporated seamlessly into the clinical workflow. Therefore, the initial user-centered design was augmented by interaction design using patient-centered and participatory decision aid development. An interaction designer (MB) joined the research team. Subsequent rounds involved rapid prototyping and low-fidelity wireframing. This enhanced approach focused on tool usefulness (and lack of use by test subjects). Interview responses revealed users were not using the tool because the tool was overly prescriptive with too much text on the screen that interrupted or distracted from conversation with patients. Earlier prototypes were over-designed, which forced clinicians to give more attention to the tool than the patient or to abandon the tool. Eliminations included the patient section with educational materials for patient review prior to the clinician's evaluation (based on previous qualitative findings that patients come to the ED for a clinician's expert evaluation) and a patient demographic survey and questionnaire about the injury. Revisions dramatically reduced the number of screen taps, checkboxes, and data entry. Furthermore, the Concerns section expanded to 6 boxes a patient could select to discuss . This minimalist version allowed clinicians to adapt the tool to their practice style and patient-specific education. It reassured patients by providing structure to the clinical conversation with cues (eg, How soon can I get back to work?). The tool was less prescriptive and increased the likelihood of implementation.

Field Testing

Field testing was conducted with 10 patients. Additional incremental revisions were made to the prototype. Observation and analysis of use in the ED context and application of ecological interface design principles distilled the workflow for the final Concussion or Brain Bleed app. This further elucidated important patient issues. The final app now supports the clinician's decision and patient engagement and education around patient-specific risk about head injuries, CT imaging, counseling, and patient concerns. Data entry was streamlined, and explicit user input was nearly eliminated. Grouping risk categories provides the clinician with the patient's individualized risk assessment by a single tap of the screen. This efficient Canadian CT Head Rule display gives the clinician more time for risk communication with the patient. The risk visualization format and content underwent revisions from the initial prototype through usability and field testing. The initial prototype used text-based risks (eg, clinically important brain injury). Later versions used pictographs, plain language, absolute risks with a constant denominator,

and a color scheme to differentiate the 4 categories of patient-centered outcomes. A key finding was how important it is to teach and emphasize that a concussion is not visible on CT. The tool evolved into helping patients understand specific recommendations and their implications. The Risk Discussion section offers plain language on the utility (or lack thereof in low-risk patients) of CT as well as cues to discuss concussion and the individual patient's concerns.

Beta Testing

Beta testing was conducted over 6 weeks with 4 attending emergency physicians in the care of 7 low-risk, minor head injury ED patients. The final Considerations section for low-risk patients was revised based on user feedback that it was too busy. Prior to beta testing, this section had a wall of text including a large inventory of sections that could be discussed at the clinician's discretion. Beta testing revealed just a checklist with the option to expand sufficed. The section's content remained relatively unchanged with the format converted to a checklist with single-tap dropdown options that provided more information (via hypertext) when specifically selected. Readability increased with limited distractions while remaining flexible to differing clinician practice styles and individual patient needs. We developed a work-around for integration with EHR workflow using Epic (Epic Systems Corp) SmartPhrases. This charting tool allows clinicians to auto-populate text using shorthand. SmartPhrases allow rapid documentation of use of the Concussion or Brain Bleed app in the EHR.

Aim 3

We enrolled 41 of 43 identified patients (see Figure 1; recruitment rate 95%) in the 6-week study period with a mean age of 34.9 years (range 18-59). The majority of patients were female (26, 63%), were not of Hispanic or Latino origin (31, 76%), and identified high school or general educational diploma or less as their highest level of education (24, 59%). The mean patient subjective literacy score was 12.4 (SD 2.8), and mean subjective numeracy score was 30.4 (SD 8.5). Of 33 eligible clinicians, 29 (recruitment rate 88%) caring for eligible patients agreed to participate. The mean clinician age was 34 years (range 24-51; see Table 2). The majority of clinicians were female (15, 52%), not of Hispanic or Latino origin (36, 90%), white (20, 69%) and physicians (MDs) (16, 55%). There were 11 (38%) clinicians with a Physician Assistant degree and 2 (7%) with an Advanced Practice Registered Nurse (nurse practitioner) degree. The mean (range) years of experience practicing emergency medicine (including residency) was 5.8 (0-24). All clinicians owned a personal smartphone (29, 100%) and most owned a personal tablet computer (21, 72%). The majority of clinicians (24, 83%) also indicated they spent over 30 hours a week on a computer, tablet, or smartphone.

Patient Experience

Mean (SD) knowledge assessment scores increased from 3.3 (1.9) out of 9 pre-encounter to 4.7 (2.1) postencounter, with mean difference of 1.4 (95% CI 0.8-2.0). The mean (SD) patient decisional conflict score was 11.7 (13.5), and the mean (SD) trust in physician score was 92.5 (12). Both scales are from 0 to 100. Patient satisfaction scores showed that a majority of patients were satisfied with the clarity of information (35, 85%), helpfulness of the information (36, 88%), and amount of information (36, 88%). The majority of patients also said that they would recommend the app to others (36, 88%) and would want to use something similar for other clinical decisions (26, 63%). The mean (SD) fidelity score was 6.7 (1.8) out of the 8 intended actions that the app aimed to elicit. Clinicians most consistently described the different risk levels portrayed on the risk visualization pictograph (95%). Clinicians least frequently elicited the patient or caregiver's concerns (61%).

Health Care Utilization and Patient Safety

In the 41 encounters in which the app was used, 7 patients (17%) received a head CT in the ED. Since these patients were at low risk, all 7 CTs scans were not recommended based on the CCHR criteria. Of the 7 CTs, the 3 most frequently cited reasons for obtaining CT were referring physician request (5/7, 71%), mechanism of injury (3/7, 43%), and headache (3/7, 43%). In 100% of cases in which the app was used, clinicians reported they would make the same decision without the app. No patients were admitted to the hospital (0, 0%). Follow-up data were collected via phone call from 34 patients (83%), email from 4 patients (10%), and chart review for the remaining 3 patients (7%). At 7-day follow-up, 4 patients (10%) had returned to an ED, 14 patients (34%) had visited a physician's office or clinic, 1 patient (2%) did both, and 22 patients (54%) did neither. Further testing or procedures were obtained for 5 patients (12%) within 7 days following the encounter, and 2 patients (5%) underwent neuroimaging within 7 days. No patient had acute findings on CT in the ED or on follow-up imaging (0%).

Discussion & Implications

In patients with low-risk minor head injury who were being considered for CT head imaging in the ED, use of the Concussion or Brain Bleed app in this prospective interventional pilot study resulted in increased patient knowledge and was associated with a low rate of CT use, high trust in the physician, low patient decisional conflict, high clinician Net Promoter Score, and high system usability score without any adverse events in patients. We found the app to be acceptable to both patients and clinicians.

Comparison with Other Studies

Our trial's setup was similar to those of other ED shared decision-making trials for adult patients with chest pain and pediatric patients with head injury. The high trust in physician and low decisional conflict scores reported here establish baseline efficacy of the Concussion or Brain Bleed app. These scores are consistent with those of previous ED trials of paper-based decision aids for adult ED patients with chest pain (trust in physician: mean 89.5, SD 13.4 versus this study, 92.5, SD 12.0; decisional conflict: mean 43.5, SD 11.3 versus this study, 11.7, SD 13.5) and parents of pediatric ED patients with head injury (results to be reported soon). Although the results have not yet been formally reported, our population had similar but slightly lower literacy and numeracy than the trial studying parents of pediatric ED patients with head injury described in the Outcome Measures subsection above.

Traditional implementation strategies lead to increased CT use in minor head injury [33]. On the other hand, traditional CDS has had only a modest effect (5%-8%) on decreasing the rate of CT overuse (35%) in these patients . The overuse rate in our study of 17% cuts this rate in half. Based on our previous qualitative work, we hypothesize that this additional decrease was due to the intervention's ability to engage patients and address nonclinical factors (eg, identifying and addressing patient concerns and increasing physician trust). However, the number of patients enrolled in this study was limited and was a convenience sample.

The intervention's System Usability Scale and Net Promoter scores were also high. To put them in context, a system usability score of 85.1 has been correlated with the adjective rating of "excellent" or a grade of A+. Amazon.com is a frequently used website that has been found to have a similar system usability score. Furthermore, the Net Promoter Score of 36.6 indicates a greater rate of users who were promoters than detractors of the product and, therefore, suggests the product's growth potential.

Meaning of the Study

Overuse of CT in minor head injury is complex and multifactorial, including both clinical and nonclinical contributing factors. Traditional implementation strategies such as CDS can address clinical factors such as a lack of awareness of the evidence. However, these strategies have had limited success for this decision, likely due to nonclinical factors such as patients' concerns with their condition and care. Findings of this study suggest that patients can be educated and engaged in the ED setting in decisions about CT imaging for low-risk minor head injury using a health information technology interface that supports the clinician-patient relationship (rather than getting in its way). Specifically, if these findings are confirmed in a larger effectiveness trial,

it would imply that successful adoption of the Concussion or Brain Bleed app could help address nonclinical factors that contribute to overuse of CT in minor head injury that are not addressed with traditional implementation strategies and traditional CDS.

In conclusion, this study has shown that it is feasible to use an integrated decision aid with CDS on a tablet computer at the bedside in the ED to engage, educate, and reassure low-risk minor head injury patients about CT and concussion. aAn app to help patients assess the utility of CT imaging after head injury in the ED increased patient knowledge, was associated with a low rate of CT overuse, and was reported to be “extremely helpful” to patients. The high degree of patient satisfaction and clinician acceptability, and high system usability scores are evidence to support the need for rigorous testing of the app in future research that could optimize its implementation into routine ED care and measure its effectiveness compared with usual care.

Unanswered Questions and Future Research

In this pilot study, research staff were available to coordinate use of the Concussion and Brain Bleed app in appropriate patients. Given the competing demands in the ED context, in the absence of research staff there would be multiple barriers to its use, adoption, and integration into routine ED care. Although clinicians reported in every use of the intervention that the app did not affect their clinical decision whether to obtain CT imaging, we maintain that the Concussion or Brain Bleed app has the potential to safely reduce CT imaging in low-risk minor head injury patients. Future research should focus on assessing and optimizing the context for implementation of the Concussion or Brain Bleed app into routine ED care. Identifying barriers and facilitators for how best to embed this complex innovation as part of routine care could optimize its reach, effectiveness, adoption, implementation, and maintenance in routine care. For example, a qualitative analysis could explore the reasons that some physicians approved of the tool but would not recommend it to others. Once these factors are identified and optimized, our plan to compare the effectiveness of the app versus usual care could more fully determine its effects on patient experience, clinician experience, health care utilization, and patient safety. If the app is effective, our next goal would be to scale the intervention for dissemination and implementation to outside sites. At the time of this report, the Concussion or Brain Bleed app is also being adapted for use in Canada and Rhode Island with plans to study it there in a comparative effectiveness trial as well.

6. List of Publications and Products

The primary product of this award is the Concussion or Brain Bleed app which is hosted at https://b2b.med.yale.edu/ and intended for viewing on a tablet computer (with 1536 × 2048

resolution). Publications directly related to the K award project as well as those related to training activities associated with the award are listed here:

1. Melnick ER, Shafer K, Rodulfo N, et al. Understanding Overuse of Computed Tomography for Minor Head Injury in the Emergency Department: A Triangulated Qualitative Study. Acad Emerg Med 2015 Dec;22(12):1474–1483. PMID:26568523

2. Melnick ER, Lopez K, Hess EP, et al. Back to the Bedside: Developing a Bedside Aid for Concussion and Brain Injury Decisions in the Emergency Department. EGEMS (Wash DC) 2015 Jun 29;3(2):1136. PMID:26290885

3. Melnick ER, Keegan J, Taylor RA. Redefining Overuse to Include Costs: A Decision Analysis for Computed Tomography in Minor Head Injury. Jt Comm J Qual Patient Saf 2015 Jul;41(7):313–322. PMID:26108124

4. Melnick ER. How to make less more: empathy can fill the gap left by reducing unnecessary care. BMJ 2015 Nov 4;351:h5831. PMID:26537887

5. Le Grand Rogers R, Narvaez Y, Venkatesh AK, ..., Melnick ER. Improving emergency physician performance using audit and feedback: a systematic review. Am J Emerg Med 2015 Oct;33(10):1505–1514. PMID:26296903

6. Moore CL, Broder J, Gunn ML, ..., Melnick ER, et al. Comparative Effectiveness Research: Alternatives to “Traditional” Computed Tomography Use in the Acute Care Setting. Acad Emerg Med 2015 Dec;22(12):1465–1473. PMID:26576033

7. Melnick ER, O’Brien EGJ, Kovalerchik O, et al. The Association Between Physician Empathy and Variation in Imaging Use. Acad Emerg Med 2016 Aug;23(8):895–904. PMID:27343485

8. Melnick ER, Probst MA, Schoenfeld E, et al. Development and Testing of Shared Decision Making Interventions for Use in Emergency Care: A Research Agenda. Acad Emerg Med 2016 Dec;23(12):1346–1353. PMID:27457137

9. Melnick ER, Powsner SM. Empathy in the Time of Burnout. Mayo Clin Proc 2016 Dec;91(12):1678–1679. PMID:27836111

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11. Fleischman W, Ross JS, Melnick ER, et al. Financial Ties Between Emergency Physicians and Industry: Insights From Open Payments Data. Ann Emerg Med 2016 Aug;68(2):153–158.e4. PMID:26973175

12. Probst MA, Kanzaria HK, Schoenfeld EM, ..., Melnick ER, et al. Shared Decisionmaking in the Emergency Department: A Guiding Framework for Clinicians. Ann Emerg Med 2017 Nov;70(5):688–695. PMID:28559034

13. Gellert G, Webster S, Gillean J, Melnick E*, et al. Should US doctors embrace electronic health records? BMJ 2017 Jan 24;356:j242. PMID:28119282 [* co-first author]

14. Melnick ER, Hess EP, Guo G, et al. Patient-Centered Decision Support: Formative Usability Evaluation of Integrated Clinical Decision Support With a Patient Decision Aid for Minor Head Injury in the Emergency Department. J Med Internet Res 2017 May 19;19(5):e174. PMID:28526667

15. Singh N, Hess E, Guo G, ..., Melnick E. Tablet-Based Patient-Centered Decision Support for Minor Head Injury in the Emergency Department: Pilot Study. JMIR Mhealth Uhealth 2017 Sep 28;5(9):e144. PMID:28958987

16. Melnick ER. Big Versus Small Data and the Generalizability of the Rate of Computed Tomography Overuse in Minor Head Injury. Acad Emerg Med 2017 Mar;24(3):391–392. PMID:27617902

17. Melnick ER, Powsner SM, Shanafelt TD. In Reply-Defining Physician Burnout, and Differentiating Between Burnout and Depression. Mayo Clin Proc 2017 Sep;92(9):1456–1458. PMID:28870365

18. Sharp AL, Huang BZ, Tang T, ..., Melnick ER, et al. Implementation of the Canadian CT Head Rule and Its Association With Use of Computed Tomography Among Patients With Head Injury. Ann Emerg Med 2018 Jan;71(1):54–63.e2. PMID:28739290

19. Mbachu SN, Pieribone VA, Bechtel KA, ..., Melnick ER. Optimizing recruitment and retention of adolescents in ED research: Findings from concussion biomarker pilot study. Am J Emerg Med 2018 May;36(5):884–887. PMID:28918968